

HHS SBIR RFA-HD-15-006

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The official link for this solicitation is: <http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-15-006.html>

Agency:

Department of Health and Human Services

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December 17, 2014

Solicitation:

[RFA-HD-15-006](#)

Close Date:

December 17, 2014

Topic Number:

RFA-HD-15-006

Description:

Purpose

This Funding Opportunity Announcement (FOA) invites Small Business Innovation Research (SBIR) grant applications from small business concerns (SBCs) to propose research to develop tools and technology for diagnosis, intervention and improvement of outcomes for pregnancies and infants with known neurologic disease or infants at high risk for neurologic complications.

Background

Improving pregnancy outcome is a prime mission for *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ([NICHD](#)). Neonatal neurologic disease contributes a significant burden to patients, their families and society. Neonatal encephalopathy (NE) affects up to 3.3/1000 term and late preterm infants in the developed world. Hypoxic ischemic encephalopathy (HIE), a subset of neonatal encephalopathy, affects 1-2/1000 infants per year. Cerebral palsy (CP) is one of the outcomes associated with NE and HIE, and approximately 30% of term and late preterm CP will have neonatal encephalopathy. The prevalence of CP is 2/1000 live births and approximately two thirds are born at term or late preterm. Premature infants, infants with metabolic disease, and sequelae of complications in the neonatal period can lead to significant neurologic morbidity. Technologies to assess pregnancies at risk for infants with deleterious neurologic outcomes as well as tools to treat such infants are needed to affect outcome. A workshop held in May 2013 at NICHD highlighted the need for continued support.

Objectives

The goal of this initiative is to develop tools and technology for diagnosis, intervention and improvement of outcomes for pregnancies and infants with known neurologic disease or infants at high risk for neurologic complications. There is a need to foster collaboration between clinical and bioengineering research investigators in the field of tools and technologies for assessment of pregnancies and infants with or at risk of neurologic complications. This FOA invites SBCs to propose innovative research that can lead to development of non-invasive, or minimally invasive, instruments, devices, tools, and technologies to assess, monitor, and treat women during pregnancy as well as neonates and infants with or at high risk for neurologic problems.

Research Objectives and Scope

Projects involving biomarker identification, and development of tools to screen, prognosticate, and diagnose high risk and at risk pregnancies and infants, novel neuroprotective agents and strategies, as well as interventions for neurologic disorders would be deemed responsive to this initiative.

Specific areas of interest could include, but are not limited to:

- Assessment of fetal neural integrity
- Intrapartum neurologic assessment and monitoring
- Neuroprotective resuscitation tools
- Novel methods of monitoring and delivering hypothermic neural rescue, particularly during high risk transport
- Novel strategies to improve neurologic function in infants affected with neurologic conditions, particularly those infants at highest risk for cerebral palsy
- Non-invasive or minimally invasive tools of assessment of neurologic function including blood flow, oxygen delivery and utilization, seizure detection and management, and methods to monitor other systemic organ functions in high-risk infants affected by neurological illnesses; simple tools to assess status of sleep and wakefulness; and physiologic function
- The tools and methods to screen special sensory systems (visual, auditory, tactile, and olfactory); and tools to assess and grade pain perception
- Tools and methods to assess the integrity of the autonomous nervous system, including studies related to the study of gut motility and function

The proposed studies should establish the accuracy and safety of the tool being developed under varied clinical conditions. Studies may range from concept to developmental phases, with the goal of developing technologies that can be marketed, and used in regular clinical settings for pregnant women and newborn infants.